QUINN EMANUEL URQUHART & SULLIVAN, LLP
Robert W. Stone (Bar No. 163513)
robertstone@quinnemanuel.com
Michael D. Powell (Bar No. 202850)
mikepowell@quinnemanuel.com
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, California 94065
Telephone: (650) 801-5000
Fax: (650) 801-5100

Adam B. Wolfson (Bar No. 262125)
adamwolfson@quinnemanuel.com
50 California Street, 22nd Floor
San Francisco, California 94111
Telephone: (415) 875-6600
Fax: (415) 875-6700

Attorneys for Defendant Corcept Therapeutics, Incorporated

DUANE MORRIS LLP
Lucas C. Wohlford (admitted *Pro Hac Vice*)
100 Crescent Court, Suite 1200
Dallas, TX 75201
Telephone: +1 214 257 7200
Facsimile: +1 214 257 7201
E-Mail: lwohlford@duanemorris.com

Attorney for Defendant Optime Care Inc.

[Additional Counsel Listed On Signature Page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

vs.

CORCEPT THERAPEUTICS, INC., et al.,

Defendants.

Case No. 5:24-cv-03567-NW

Honorable Noël Wise

DEFENDANTS' SUPPLEMENTAL BRIEF REGARDING STATUTE OF LIMITATIONS ISSUES IN FURTHER SUPPORT OF JOINT MOTION TO DISMISS

Pursuant to the Court's August 4, 2025 order (Dkt. 121), Defendants respectfully submit this supplemental brief and chart (attached as Ex. A) in support of their joint motion to dismiss Teva's First Amended Complaint with prejudice. In response to the Court's questions, substantially all of Teva's claims and theories are time-barred and also fail for the additional grounds described in Defendants' motion.

I. TEVA'S FEDERAL ANTITRUST CLAIMS (COUNTS I–III)

The federal antitrust statute of limitations is four years. 15 U.S.C. § 15b. That means, absent an exception, Teva's claims are untimely if they accrued before **June 13, 2020**, four years before it filed this action. *Garrison v. Oracle Corp*., 159 F. Supp. 3d 1044, 1065–66 (N.D. Cal. 2016).

Orange Book Listing Claims. Teva challenges Corcept's listing of the '348 and '495 patents, but the listings occurred (and any liability based on them accrued) on **January 27, 2015** and **November 28, 2017**, respectively. Dkt. 39 ("FAC") ¶ 82. Thus, any liability based on those claims expired four years later, on **January 27, 2019** ('348 patent) and **November 28, 2021** ('495 patent), well before the applicable limitations period here. *Garrison*, 159 F. Supp. 3d at 1065–66 (federal antitrust claims "accrue under the default accrual rules at the time of the alleged anticompetitive conduct"). Corcept also brought suit against Teva based on the '348 and '495 patents on **March 15, 2018** (FAC ¶ 76), meaning any antitrust claims based on that lawsuit similarly expired well before the limitations period here: *i.e.*, by **March 15, 2022**. Teva challenges no other Orange Book listings.

The continuing violation doctrine does not save Teva's Orange Book claims. Dkt. 55 ("MTD") at 7; Dkt. 68 ("Reply") at 8. A timely act or injury related to one antitrust liability theory does ***not*** suddenly render other untimely theories actionable simply because a plaintiff asserts them in the same lawsuit. As the Supreme Court explained in *Klehr v. A.O. Smith Corp*., 521 U.S. 179 (1997), a "plaintiff cannot use an independent, new predicate act as a bootstrap to recover for injuries caused by other earlier predicate acts that took place outside the limitations period." *Id.* at 190. This is because "the commission of a separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period." *Id*.; *see also Arcell v. Google LLC*, 2023 WL 5336865, at *5 (N.D. Cal. Aug. 18, 2023) (an antitrust plaintiff may only sue and obtain "relief for injuries occurring from that overt act within the statute of limitations");

Stanislaus Food Prod. Co. v. USS-POSCO Indus., 2010 WL 3521979, at *15–*17 (E.D. Cal. Sept. 3, 2010) (antitrust claim based on "formulation and maintenance of UPI" dismissed as time-barred because "[t]hat plaintiff also alleges additional, later restraints of trade, does not alter that the statute of limitations has run on the formation and maintenance of UPI").

Nor does the "speculative damages" exception save these claims. As an initial matter, the FAC did not plead facts establishing that exception, so it is waived. Reply at 7; *accord Perrigo Co. v. AbbVie Inc*., 2022 WL 2870152, at *5 n.12 (3d Cir. July 21, 2022) (rejecting arguments based on exception not raised in pleading). Moreover, Teva cannot meet the exception because Teva felt any alleged injury from the Orange Book listings—preclusion from the market due to the 30-month stay—by March 2018 (when Corcept's lawsuit over the two Orange Book patents triggered the stay).[1] Reply at 7; *Perrigo*, 2022 WL 2870152, at *4–*5 (exception inapplicable to generic manufacturer's antitrust claims based on Orange Book patent listings, as "impact felt" when "FDA approval [is] put on hold as soon as Defendants file[] the Litigation" based on Orange Book listings); *see also CSX Transportation, Inc. v. Norfolk S. Ry. Co*., 114 F.4th 280, 290–291 (4th Cir. 2024) (discussing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979) for this point).[2]

Sham Litigation Claims. Teva's claims predicated on alleged sham litigation accrued when those lawsuits were filed and the patents asserted. MTD at 9, 11 & Reply at 10–11. Based on those dates and the four-year limitations period, Teva's claims and injuries are time-barred for at least seven of the nine at-issue patents accruing and expiring as follows: '348 and '495 patents, **March 15, 2018** and **March 15, 2022** (FAC ¶ 76); '526 patent, **July 6, 2018** and **July 6, 2022** (FAC ¶ 120); '214, '242, and '243 patents, **February 8, 2019** and **February 8, 2023** (FAC ¶¶ 116, 120); '216 patent,

[1] Even if Teva's Orange Book and/or other sham litigation, exclusive dealing, and bribery claims based on 2018 and earlier conduct individually or collectively (as a "scheme") accrued on February 17, 2019 when Corcept's Orphan Drug Exclusivity expired, Teva would have had to bring such claims within four years by February 17, 2023, but it waited to do so until June 13, 2024, so they are barred.

[2] Moreover, a generic manufacturer's lack of FDA approval does not preclude it from bringing antitrust claims (and thus does not stop the clock for the same) against the brand manufacturer, particularly where the brand's conduct is what allegedly caused the generic's delay in or lack of approval. Reply at 7–8. Outside this litigation, Teva knows this, because it, as a generic, has brought such claims against brand manufacturers before receiving FDA approval. *Abbott Lab'ys v. Teva Pharms. USA, Inc*., 2022 WL 34347571, Case No. 02-cv-1512 (D. Del.), Dkt. 20 at ¶¶ 103, 107, 163–66 (counterclaims). Defendants further address Teva's FDA approval and speculative damages arguments and cited cases (which do not support Teva), in their Reply. Reply at 7–8.

December 13, 2019 and **December 13, 2023** (FAC ¶¶ 116, 120). Teva did not need to wait until these underlying lawsuits concluded to assert they were shams, and, by doing so, its claims based on the assertion of these patents are now time-barred. Reply at 10–11 (collecting authority). Teva knows this: in Corcept's underlying patent cases, Teva quickly asserted (***before*** the cases concluded), for example, that Corcept's assertion of the patents was "baseless" and meant to delay Teva's generic (Case No. 2:18-cv-3632 (D.N.J.), Dkt. 37 at ¶¶ 28–29), and Teva has (as generics often do) asserted sham litigation antitrust counterclaims in underlying patent litigation without waiting until that litigation concludes. *See, e.g.*, *Abbott*, Case No. 02-cv-1512 (D. Del.), Dkt. 20 at ¶ 136.

The continuing violation doctrine does not save Teva's sham litigation claims based on the '348, '495, '526, '214, '242, '243, and '216 patents. Reply at 11. These patents were all asserted by December 2019—before the four-year period preceding Teva's filing this case (June 13, 2020)—so they cannot be timely overt acts as to themselves. Moreover, to the extent Corcept asserted the two remaining patents ('800 and '801) during that four-year period, those actions, at best, create new causes of action for sham litigation over ***only*** those two patents, and do not "permit [Teva] to recover for the injury caused by old overt acts outside the limitations period." *Klehr*, 521 U.S. at 190. Moreover, under *Klehr*, *Stanislaus*, and the like, later limitations period acts or injuries based on Teva's ***other*** theories do not render timely ***sham litigation*** claims based on these seven patents.

The unpled speculative damages exception also does not apply. Reply at 10. At the time Corcept filed its suits on these patents, the alleged injury from the litigation was apparent (not uncertain). For the March 2018 lawsuit regarding the '348 and '495 patents, the alleged harm was the Hatch-Waxman 30-month stay, which Teva felt immediately. *Perrigo*, 2022 WL 2870152, at *4–*6. As for the five other pre-limitations period patent claims, Teva alleges only the conventional harms of costs associated with defending any lawsuit, like being "tie[d] up … in litigation," FAC ¶ 120, which were also felt immediately. The "key question" is "whether the existence of the harm is determinable, not the specific dollar value of that harm." *Ryan v. Microsoft Corp*., 2015 WL 1738352, at *12–*13 (N.D. Cal. Apr. 10, 2015) (Koh, J.) (cleaned up) (dismissing claim). The answer here is yes, and Teva's lack of FDA approval before 2020 does not require otherwise: there is no bar on a generic manufacturer asserting sham litigation claims against a brand manufacturer prior to FDA

approval (as occurred in *Perrigo* and other cases), and indeed Teva has done so itself. *See supra*; Reply at 7–8, 10–11.

Exclusive Dealing Claims. Teva's claims predicated on exclusive dealing are based on an August 4, 2017 contract between Corcept and pharmacy Optime. To try to meet the substantive requirements for exclusive dealing, Teva alleges the agreement "has been in place since August 4, 2017" and (importantly for this brief) is "an 'evergreen' contract" subject to "automatic renewal" and with "no expiration date." FAC ¶¶ 137, 139. These allegations confirm the claim is stale, because Teva failed to challenge the agreement until seven years later.

Teva argues that it could not have challenged the exclusive dealing agreement prior to its market entry in 2024, or prior to its final FDA approval in August 2020, because it supposedly needed final approval before it could sue for alleged blocking conduct. Opp at 17–18. This is incorrect as a matter of law. A prospective generic entrant can bring good faith antitrust claims—even without FDA approval—as soon as it can allege its "intent and preparedness" to enter the market. *See Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808 (D.C. Cir. 2001) (holding a generic manufacturer has standing to sue for exclusionary conduct "even before the FDA approve[s] [its] ANDA," so long as it can "allege[] its intent and preparedness to enter the market by claiming that FDA approval was probable."). Teva alleges it had that "intent and preparedness" no later than **October 2018**. FAC ¶¶ 73, 79, 204. Thus, Teva's exclusive dealing claim accrued no later than October 2018, and the claim is time-barred because Teva failed to bring it before October 2022.[3]

Teva's argument that an earlier lawsuit would have been too speculative is also wrong. As

[3] Teva's cases (Opp. 17–18) are not to the contrary. *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, holds that antitrust claims accrue when a defendant's conduct allegedly harms competition and the plaintiff. 401 U.S. 321, 339 (1971). The Optime contract allegedly began excluding Teva the moment Teva alleges it was prepared to enter the market: October 2018. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, confirms a competitor plaintiff without FDA approval can sue based on "intent-and-preparedness" to enter. 2009 WL 10674453, at *2–3 (C.D. Cal. May 15, 2009); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 2009 WL 8727693, at *14 (C.D. Cal. Feb. 17, 2009); *see also* Reply at 7–8. As noted, Teva alleges it had that in 2018 (FAC ¶¶ 44, 77). *Corner Post, Inc. v. Bd. Of Governors of Fed. Rsrv. Sys.*, is an Administrative Procedures Act, not antitrust, case and therefore addresses statutes of limitations for the APA. Finally. *Ethypharm S.A. France v. Abbott Lab'ys*, found no standing as the foreign plaintiff's domestic distributor sought FDA approval. It also noted that where, as here, the manufacturer already submitted information "for FDA approval," it had standing. 707 F.3d 223, 225–31, 236 n.20 (3d Cir. 2013).

Andrx noted, it is ***not*** speculative for a generic manufacturer with "intent and preparedness" to sue prior to market entry, particularly when the generic manufacturer in question (like Teva) "was not an inexperienced newcomer; it already manufactured generic pharmaceuticals. It had already developed its product and, once FDA gave tentative approval to its ANDA, was simply waiting out [the] exclusivity period." *Id.* at 815. Teva alleges these facts as of October 2018. FAC ¶¶ 73, 77, 79, 204.

The continuing violation doctrine does not save Teva's claim. While it contends the parties renewed and amended the contract, Teva alleges that the ***exclusivity term*** it challenges has remained "in place" since 2017 and was subject to "***automatic renewal*** on three-year terms." FAC ¶¶ 137, 143. These allegations are fatal. *See Ryan*, 147 F. Supp. 3d at 884–85 ("maintenance and renewal" of "preexisting" agreement insufficient). Nor does Teva point to any distinct injuries—separate from those flowing from the unchanged exclusivity term—that arise from any automatic renewals or amendments.

Claims Predicated on Bribery. Teva alleges that Corcept has been paying supposed kickbacks to prescribers at least as early as 2016. FAC ¶ 168. For the reasons discussed above, at the very least, any antitrust claims or injuries based on supposed payments before **June 13, 2020** are time-barred (and the bribery based claims and theories, regardless of time period, fail for additional reasons).

II. TEVA'S STATE LAW CLAIMS (COUNTS IV–VII)

Teva's UCL, Section 16600, and unjust enrichment claims are time-barred for the same reasons as its antitrust claims. Where parties assert Sherman Act claims alongside California state law claims, courts "address [the] Sherman Act claim to resolve when [the] Sherman Act and California law claims accrued." *Garrison*, 159 F. Supp. 3d at 1064–65 (evaluating timeliness of Sherman Act, UCL, and Section 16600 claims together). Similarly, where, as here, state law antitrust and consumer protection laws are "based on the same allegations" as defective Sherman Act claims, they are dismissed alongside the Sherman Act claims. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139–40 (E.D.N.Y. 2003). Teva's omnibus state law claim, like its federal antitrust claims, is therefore similarly time-barred. In addition, besides limitations issues the Court has raised (Dkt. 121), all of these state law claims fail on additional grounds. MTD at 25–30; Reply at 16–18.

DATED: August 7, 2025

By: */s/ Robert W. Stone*

QUINN EMANUEL URQUHART & SULLIVAN, LLP
Robert W. Stone (Bar No. 163513)
robertstone@quinnemanuel.com
Michael D. Powell (Bar No. 202850)
mikepowell@quinnemanuel.com
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, California 94065
Telephone: (650) 801-5000
Fax: (650) 801-5100

Adam B. Wolfson (Bar No. 262125)
adamwolfson@quinnemanuel.com
50 California Street, 22nd Floor
San Francisco, California 94111
Telephone: (415) 875-6600
Fax: (415) 875-6700

Brantley I. Pepperman (Bar No. 322057)
brantleypepperman@quinnemanuel.com
865 South Figueroa Street, 10th Floor
Los Angeles, CA 90017-2543
Telephone: (213) 443-3000
Fax: (213) 443-3100

Steig D. Olson (admitted *pro hac vice*)
steigolson@quinnemanuel.com
51 Madison Avenue, 22nd Floor
New York, New York 10010
Telephone: (212) 849-7000
Fax: (212) 849-7100

Attorneys for Defendant Corcept Therapeutics, Incorporated

DUANE MORRIS LLP
Lucas C. Wohlford (admitted *Pro Hac Vice*)
100 Crescent Court, Suite 1200
Dallas, TX 75201
Telephone: +1 214 257 7200
Facsimile: +1 214 257 7201
E-Mail: lwohlford@duanemorris.com

Justin J. Fields (SBN 259491)
One Market Plaza, Suite 2200
San Francisco, CA 94105-1127
Telephone: +1 415 957 3000
Facsimile: +1 415 957 3001
E-Mail: jfields@duanemorris.com

Attorney for Defendant Optime Care Inc.

CIVIL LOCAL RULE 5-1 ATTESTATION

I, Robert W. Stone, am the ECF user whose credentials were utilized in the electronic filing of this document. In accordance with Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of this document has been obtained from each of the signatories listed above.

DATED: August 7, 2025

By */s/ Robert W. Stone*
Robert W. Stone

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of August 2025, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System, causing it to be electronically served on all attorneys of record.

By */s/ Robert W. Stone*
Robert W. Stone